K133490
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DEC 30 2013

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

Submitter Information

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Date: November 12, 2013

Trade Name: G-scan Brio

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90LNH

Predicate Device(s)

Trade Name	Common name	Class	Product code	Manufacturer	K number
G-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K122006

510(k) Summary
G-scan Brio
Esaote S.p.A.

Device Description

The changes performed on the modified G-scan Brio, with respect to the cleared version – G-scan Brio K122006 – are due to the improvement of the system performance. These modifications, which do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

- PC Unit with GPU Card and LCD monitor NEC model P242W

- A new Software version including the following features:
  1. 3D acquisitions: SpeedUp technique
  2. 3D acquisitions: Elliptical filling of k-space technique
  3. Myelographic contrast technique

- A new operating system and database engine:
  1. Operating system Microsoft Windows VISTA Ultimate 64 bit platform
  2. Database based on the built-in Microsoft SQL Server database Engine

Intended Use(s)

G-scan Brio is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip, imaging the temporomandibular joint and imaging the cervical spine and the lumbar spine sections as portions of the spinal column.

G-scan Brio images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.

Technological Characteristics

The modifications reflected in this Special 510(k) for the G-scan Brio system are to improve system performance. The modifications have not altered the fundamental scientific technology of the unmodified version, G-scan Brio K122006.

Summary of Non-Clinical Tests

The G-Scan Brio has been evaluated to demonstrate substantial equivalence related to medical electrical equipment, risk management, software verification and validation, and image quality and has been found to conform to the following medical device safety standards:

- IEC 60601-1-1
- IEC 60601-1-2
- ISO 14971
- ISO 62304
- NEMA MS-1

Summary of Clinical Tests

No clinical tests were performed.

Conclusion

The non-clinical testing demonstrates that the G-Scan Brio is as safe, as effective, and performs as well as or better than the predicate. G-Scan Brio is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 30, 2013

Esaote, S.p.A.
% Allison Scott, RAC
Navigant Consulting, Inc.
9001 Wesleyan Road, Suite 200
INDIANAPOLIS IN 46268

Re: K133490
Trade/Device Name: G-scan Brio
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 12, 2013
Received: November 13, 2013

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133490

Device Name
G-Scan Brio

Indications for Use *(Describe)*
G-scan Brio is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip, imaging the temporomandibular joint and imaging the cervical spine and the lumbar spine sections as portions of the spinal column.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara